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Intervention

The evaluation of an intervention based on the application of patient self-completion concordance forms in Dutch community pharmacies and the effect on adherence to chronic medication

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ABSTRACT

Objective: To evaluate the use of patient self-completion concordance forms and to determine the effect of patient counselling by using concordance forms on adherence to chronic medication.
Methods: Patients with a prescription for new chronic treatment were randomised in an intervention or control group. The intervention group received a concordance form to fill in at home and to discuss during a consultation 2 weeks later in the pharmacy. The control group received the usual information and instruction on how to use the medicine. Afterwards, all patients were asked to fill in a questionnaire about their use of medicines and contact with the pharmacy employees. Adherence to the medicine was determined using rates of prescription refills after 6 months of use.
Results: The questionnaires showed that patients were satisfied about the concordance model. After 6 months of use, 79% of the patients from both intervention and control group were defined as adherent.
Conclusions: There was no significant difference found in adherence between intervention and control group.
Practice implications: Use five selected questions from the concordance form which provided most answers. Focus on one drug group and have more consultation moments.

1. Introduction

Adherence to chronic medication is important for effective treatment. However, poor adherence is a significant problem for chronic medication use. According to the literature, the adherence to medication in developed countries is 50% after 1 year [1–3]. To reach a higher degree of adherence, it is important to involve the patient in a decision about starting (chronic) therapy [4].

According to Barnett et al. [5], patient participation in medication counselling is a necessary element for the provision of pharmaceutical care. Motivating patients to write down questions to ask the pharmacist results in more patient and pharmacist satisfaction with the information given. During communication with doctors, patients lack the opportunity to express their concerns, expectations, and beliefs [6]. Therefore, the more questions doctors ask the more content patients are with their medication. Another study [7] describes the effect of encouraging patients to raise issues and to discuss symptoms and other health-related issues during a consultation with a general practitioner. Patients were provided with a leaflet to write down questions to ask the doctor, which improved patient satisfaction and perceptions of communication.

In the Netherlands, community pharmacies have changed from product-centred to more patient-centred activities [8,9]. The patient receives extensive information at the time of the initial prescription. Yet patients immediately forget 40–80% of this medical information [10]. This means it would be desirable to repeat certain information and provide feedback to help the patient remember. It is also important to discuss the indications of the medicine with the patient, in order to understand the importance of the medicine for their wellbeing. The pharmacist is, in most cases, the last professional the patient meets before actually starting to take the new medicine. Therefore, the pharmacist is the appropriate professional to answer any remaining questions the patient has about the medication. Furthermore, a study performed in Dutch community pharmacies concluded that patients who were asked to fill in a form about their

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experiences were more likely to report their drug problems in the pharmacy [11].

Hamilton et al. [12] studied the use of patient self-completion agenda forms on prescribing and adherence in general practice. The use of patient self-completion agenda forms followed by a consultation can be regarded as kind of balance sheet, as described by Janis and Mann [13]. After the consultation, where the patient receives information about the use of the medicine, the use can be discussed. Based on the advantages and disadvantages, the quality of the decision to use the medicine is increased. It is expected that this will be expressed in patient adherence to the medicine. We developed a patient self-completion agenda form for use in community pharmacy practice, the so-called concordance form. The aim of this study is to evaluate the use of patient self-completion concordance forms and patient consultations in the pharmacy using the form, and to determine the effect of the form and consultation on a patient's adherence to chronic medication.

2. Methods

The independent Ethics Committee in Leeuwarden determined that this study posed no risk to patients. The committee concluded that the Dutch law for protecting patients, who are included in a clinical trial is not relevant to this study protocol. Therefore further review was not required.

Eighteen community pharmacies, located across the Netherlands, were included. For each pharmacy, one or more employees (at least one pharmacist) took a course on treating patients in accordance with the concordance model. From May until December 2006, patients were selected according to the below mentioned inclusion and exclusion criteria.

Inclusion criteria:

- first prescription for new medicine for chronic use from selected drug class (Table 1);
- minimum age 18 years;
- consent from patient.

Exclusion criteria:

- no opportunity to guide patients personally (for example patients in nursing home);
- when patients did use the prescribed medicine before.

Table 1
Selected drug classes.

ATC-code starting with	Drug class
A02	Drugs for acid related disorders
A07	Antidiarrheals, intestinal anti-inflammatory/antiinfective agents
A10	Drugs used in diabetes
A12	Mineral supplements
B01	Antithrombotic agents
C01	Cardiac therapy
C02	Antihypertensives
C03	Diuretics
C07	Beta blocking agents
C08	Calcium channel blockers
C09	Agents acting on the rennin–angiotensin system
C10	Lipid modifying agents
G04	Urologicals
H03	Thyroid therapy
L04	Immunosuppressants
M05	Drugs for treatment of bone disease
N03	Antiepileptics
N04	Anti-parkinson drugs
N05	Psycholeptics
N06	Psychoanaleptics
R03	Drugs for obstructive airway diseases

Table 2
Questions on the concordance form.

1.	What are your expectations about the use of this medicine?
2.	What concerns do you have regarding this medicine?
3.	What problems did you experience using this medicine?
4.	What do you notice of this medicine?
5.	What would you like to know about this medicine?
6.	What would you like to know about the use of this medicine?
7.	What would be a reason for you to stop using this medicine?
8.	What opinion do family, friends and neighbours have about using this medicine?
9.	Is this the first time you get medicines to use for a longer time (more than 3 months)? yes/no If no, please mention the medicine by name?
10.	Do you have any comments or questions?
11.	How much time did it take to fill in this form?

Patients were recruited according to an application for first and second dispensing in the pharmacy computer system. The selected drug classes are mentioned in Table 1. The pharmacy determined which groups of medicines this application was used. Before the start of the study a unique number was assigned to all patients from the selected pharmacies. When patients were included according to the inclusion criteria they were randomised by the pharmacy computer system in the intervention or control group. Patients with an even number were included in the intervention group, patients with an odd number were included in the control group.

The intervention group received the usual information and instruction and a concordance form (Table 2) with questions to fill in at home after the first dispensing of the medicine. Open ended questions were used to ask for patients opinion about their use of medicines. At the second dispensing, after 2 weeks, a pharmacy employee used the completed concordance form as a basis for a patient consultation. The control group received the usual information and instruction on how to use the medicine during the first and second dispensing (Fig. 1).

In the first part of the study, the authors hypothesized that the concordance model will create improved patient satisfaction with medicines. To explore this hypothesis, we used a patient questionnaire. After the second dispensing of the medicine, both patient groups received a questionnaire to fill in at home. The questionnaire contained 12 closed questions, using an explicit format varying from 4 to 7 points. The patient was asked to mark the answer which most closely matches what they think about the proposition defined in the question. The questionnaire included questions about contact with the pharmacist or pharmacy technician as well as the advantages or disadvantages of medication use.

In the second part of the study, the authors hypothesized that extra guidance with a concordance consultation during the second dispensing of the medicine would increase adherence to that medicine after 6 months. Patients were asked for consent to collect data from the pharmacy computer system concerning dates on prescription refills. Patients using inhalers for asthma or insulin for diabetes; who stopped using the prescribed medicine after consultation with the general practitioner; or who moved and went to another pharmacy to receive their medicines were excluded for this part of the analysis because it was not possible to calculate accurate adherence. After 6 months of use, the adherence was calculated using rates of prescription refills [4]. We divided the number of days the patient received the medicine supply from the pharmacy by the number of days the medicine was prescribed. The patient was defined as adherent if the calculated medicinal drug use was $\geq$75% according to prescribed drug use. A selection of the patients also received a second questionnaire about the use of medicine after 6 months. The aim of this questionnaire was to assess reasons for possible non-adherence to the medicine.

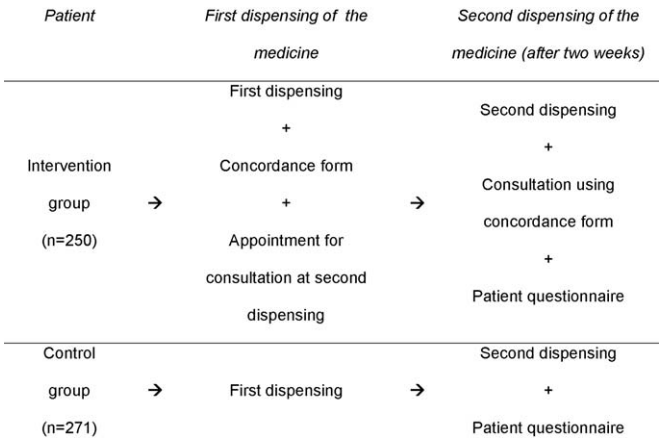

Fig. 1. Study design.

2.1. Analysis

The results were analysed using SPSS 12.0.1 for Windows. Means of the intervention and control group were compared using independent samples *t*-test. The questions on the patient questionnaire were clustered calculating Cronbach's α. Differences in adherence between the two groups were tested by a chi-square test.

The sample size calculation was based on the outcome adherence to chronic medication. The expected proportion adherent patients after 6 months in the control group was estimated to be 60% and expected to be 75% for the intervention group. For 80% power, with a one-sided 5% α, 120 patients were required in each group to identify this difference.

2.2. Privacy

All concordance forms and questionnaires were labelled with only a unique patient number in order to protect patients' privacy.

3. Results

The response rate for the patient questionnaire was 45% in the intervention group and 41% in the control group. Patients who did not return the questionnaire were excluded. After exclusion, a total of 521 patients remained, 250 patients in the intervention group and 271 patients in the control group. Side effects were mentioned mostly as possible concerns or problems on the concordance form. Other patient interests were in combination with other medicines: if it is possible to stop using the medicine at a certain time, and how long the medicine should be used. Further patient comments mostly contained comments about or answers to questions posed in the questionnaire. General comments about the concordance model were all positive.

The written answers on the concordance forms showed that there were five questions that provided most answers and were considered most relevant:

1. What are your expectations about the use of this medicine?
2. What would you like to know about this medicine?
3. What problems did you experience using this medicine?
4. What concerns do you have regarding this medicine?
5. What would be a reason for you to stop using this medicine?

The patients were also asked how much time they needed to fill in the concordance form. These results are presented in Table 3.

After the consultation with the patient, the pharmacist was asked where the consultation with the patient had taken place and how much time it took. Results are presented in Tables 4 and 5. The total number of patients is different in these tables because not all information was available for each patient.

Table 3
Time needed to fill in the concordance form.

Time (min)	*N*	%
0–10	107	74.3
11–20	24	16.7
21–30	12	8.3
31–40	0	0.0
41–50	1	0.7
Total	144	100.0

Table 4
Location where the consultation took place.

Location	*N*	%
Counter	9	5.6
Consultation room	126	78.3
Office pharmacist	24	14.9
At patients home	1	0.6
By phone	1	0.6
Total	161	100.0

Table 5
Time needed for the consultation.

Time (min)	*N*	%
0–10	84	53.2
11–20	58	36.7
21–30	13	8.2
31–40	0	0.0
41–50	2	1.3
51–60	1	0.6
Total	158	100.0

Table 6 shows the questions and the percentage response for each possible answer from the patient questionnaire.

Using Cronbach's α calculation, the questions were clustered into four groups: evaluation, attitude advantages, own effectiveness, and attitude disadvantages. There was no significant difference observed in the concordance model for the intervention group (*P*-value for each clustered group >0.2).

For the second part of this study, data from the pharmacy computer system was collected to calculate patient adherence to the medicine. After consent and exclusion of 52 patients, according to the exclusion criteria, 448 patients remained for analysis. 235 of the 448 included patients were in the intervention group with a mean (S.D.) age of 61.4 (14.9) years. In the control group were 213 patients with a mean (S.D.) age of 60.0 (14.1) years. The definition of adherence was set to a calculated drug use of $\geq$75% according to prescribed drug use. In both intervention and control group, 79% of the patients were defined as adherent. The difference was not statistically significant ($P > 0.2$).

The second questionnaire, which was sent to 281 patients, had a response rate of 51%. The first question asked which drug for chronic use the patient started 6 months ago. 63% of all respondents gave the right drug name, 24% did not answer this question, and 13% mentioned another drug name. Only the questionnaires from patients who filled in the right drug name were analysed. The second question asked if the patient still uses the medicine at the present time. A few patients (12%) mentioned that they stopped using the medicine. Data from the pharmacy computer system showed that not all patients actually stopped using the medicine but were switched to another medicine. The

Table 6
Patient questionnaire ($N = 521$).

Question	Answer categories: number of patients (%)
Evaluation ($\alpha = 0.7425$)	
1. I appreciate the attention from the pharmacist/pharmacy technician.	Yes very much: 218 (41.8%)
	Yes: 278 (53.4%)
	Yes a little: 7 (1.3%)
	Neutral: 17 (3.3%)
	No not really: 1 (0.2%)
	No: 0 (0%)
	No absolutely not: 0 (0%)
	Not answered: 0 (0%)
2. I think the consultation with the pharmacist is useful for me.	Yes very useful: 164 (31.5%)
	Yes useful: 309 (59.3%)
	Yes a little useful: 32 (6.1%)
	No not useful: 6 (1.2%)
	Not answered: 10 (1.9%)
3. The pharmacist gave me information which I can use.	Yes much: 321 (61.6%)
	Yes a little: 129 (24.8%)
	Yes very little: 25 (4.8%)
	No: 15 (2.9%)
	Not answered: 31 (6.0%)
Attitude advantages ($\alpha = 0.8318$)	
4. I think I need medication in general for my disease.	Yes definitely: 272 (52.2%)
	Yes: 169 (32.4%)
	Yes probably: 56 (10.7%)
	Neutral: 16 (3.1%)
	No probably not: 1 (0.2%)
	No: 5 (1.0%)
	No definitely not: 0 (0%)
	Not answered: 2 (0.4%)
5. I am convinced I need this medicine.	Yes definitely: 211 (40.5%)
	Yes: 194 (37.2%)
	Yes probably: 86 (16.5%)
	Neutral: 16 (3.1%)
	No probably not: 7 (1.3%)
	No: 4 (0.8%)
	No definitely not: 0 (0%)
	Not answered: 3 (0.6%)
6. The use of this medicine according to the prescription shows advantages for me (e.g. less complaints, I feel better/stronger, I can do more activities).	Yes much: 99 (19.0%)
	Yes: 263 (50.5%)
	Yes a few: 64 (12.3%)
	No: 76 (14.6%)
	Not answered: 19 (3.6%)
7. I think the advantages counts the disadvantages.	Yes absolutely: 127 (24.4%)
	Yes: 271 (52.0%)
	Yes a little: 65 (12.5%)
	No: 33 (6.3%)
	Not answered: 25 (4.8%)
8. The choice for this medicine was for me personally the best choice.	Yes the best choice: 48 (9.2%)
	Yes a good choice: 302 (58.0%)
	Yes a reasonably choice: 111 (21.3%)
	No a less good choice: 12 (2.3%)
	No a bad choice: 5 (1.0%)
	No the worst choice: 2 (0.4%)
	Not answered: 41 (7.9%)
Own effectiveness ($\alpha = 0.6418$)	
9. I think I will manage to use the medicine according the text on the label.	Yes definitely: 444 (85.2%)
	Yes probably: 63 (12.1%)
	No probably not: 4 (0.8%)
	No definitely not: 6 (1.2%)
	Not answered: 4 (0.8%)
10. I think it is important to use this medicine according the text on the label.	Yes very important: 302 (58.0%)
	Yes important: 197 (37.8%)
	Yes a little important: 13 (2.5%)
	No not important: 4 (0.8%)
	Not answered: 5 (1.0%)
Attitude disadvantages ($\alpha = 0.6368$)	
11. If I use this medicine according the prescription this will have disadvantages for me (e.g. side effects, administration route).	Yes big advantages: 17 (3.3%)
	Yes advantages: 79 (15.2%)
	Yes a few advantages: 122 (23.4%)
	No advantages: 292 (56.0%)
	Not answered: 11 (2.1%)
12. I am afraid of side effects from this medicine.	Yes very: 17 (3.3%)
	Yes: 39 (7.5%)
	Yes a little: 152 (29.2%)
	No: 302 (58.0%)
	Not answered: 11 (2.1%)

answers to the question on how the patient uses the medicine were all in agreement with the data from the pharmacy computer system. The patients who stopped or switched using the medicine were asked why they stopped or switched and most answers were related to side effects.

4. Discussion and conclusion

4.1. Discussion

The questions on the concordance form were used by the pharmacist to start the patient consultation. The answers on the questions show the patients' needs for extra information. Concerns about possible side effects were mentioned most in answers on the concordance form. This shows that patients have a need for extra information on side effects, and this will be one of the main topics discussed in the consultation. Question 10, do you have any comments or questions, did not provide extra comments or questions in addition to the answers already given on the concordance form. If patients made comments on the concordance form, they were all positive. This shows that patients are positive about the use of the concordance form as part of the concordance model at the moment they start using chronic medication. Most patients needed a maximum of 10 min to fill in the concordance form; the extra load was not too high.

The advice given in the course for pharmacy employees was to have the consultation with the patient in a consultation room in the absence of other patients for optimal privacy. More than 90% of the consultations took place in a separate room, either a consultation room or the pharmacists office.

The time needed for the patient consultation was expected to be 10 min. The use of the concordance form in the consultation was a new experience for the pharmacist and his/her team. Almost 50% of the consultations took more time than the expected 10 min. It was expected that the consultations would take less time once the team had gained more experience with the method. Some pharmacists also mentioned that the consultations took more time because patients had questions about medications other than the medicine

they just started. This took extra time, but also showed that patients have unanswered questions about their medicines. Thus these consultations with the pharmacist seemed to be useful.

A patient questionnaire was used to measure how patients think about their use of medicines. No significant result was shown for the use of the concordance model. This could be explained by the selection of patients who use medicines from different groups. It was possible that, for example, patients with diabetes thought differently about the use of their medicines compared to patients who use medication to treat hypertension. In this study, the number of patients was too small to make a division into different drug groups.

The experiences of participating pharmacy employees showed that the implementation of the concordance model does not cause any problems. The use of the concordance form was experienced as a new way of contacting the patient, and this was mentioned by the participants as positive. Pharmacists initially noted that the interaction with the patients according to the concordance form was a bit uncomfortable but that changed when they became more experienced. The use of the concordance form was mentioned as being useful in initiating the consultation with the patient. The pharmacists experienced the active consultation as pleasant and positive according to the patient.

In the second part of the study, adherence after 6 months of use was calculated. It was expected that the intervention group would have a higher percentage of adherent drug users than the control group. The percentage of adherent drug users in the control group was in fact remarkably high. From previous studies, the authors expected the adherence after 6 months to be 60% [1–3]. We hypothesized that consultations would increase adherence as had been previously reported. Gourley et al., for example, showed that for hypertensive patients receiving five consultations over a period of 6 months was more effective on adherence and general health than receiving just two consultations in the same time period [14]. One explanation for why our results did not match those of Gourley et al. could be that there was only one consultation in our study. A possible explanation for the high percentage of adherence in the control group was that the pharmacies were not randomly selected. There was an open call for recruitment, which probably attracted more motivated pharmacists. All the pharmacies were already providing pharmaceutical care using protocols for first and second dispensing, so the difference between the intervention and control group may possibly be smaller. When the adherence in the control group was already 79% it would be difficult to improve. A second explanation could be the difference in providing information to the patients within the two groups. All pharmacies had patients included in both intervention and control group. Because this was a new way of providing pharmaceutical care and the pharmacists took a course in concordance, it could be that patients in the control group also received care according to the concordance model because they were treated different compared to usual care. Third, it was difficult to measure if each pharmacist used the concordance model the same way. Because the course on concordance only took two half days, it was possible that some pharmacists were more skilled using the concordance model than other pharmacists who took the same course.

The adherence was calculated using rates of prescription refills. This was an objective method with easily obtained data. A disadvantage of this method was that the rate of prescription refill was not equivalent to ingestion of the medicine by the patient. Another disadvantage was that we could not be sure the patient received all their prescriptions from only one pharmacy [4].

Patients using medicines from various drug classes were included because the primary aim of this study was to evaluate the use of the concordance form followed by a consultation. After the beginning of the study, it was decided to also study the effect on patient adherence to the medicine. However, the number of patients included in this study was too small to divide into comparable groups to assess adherence to different medicines.

The purpose of sending out the questionnaire after 6 months of use was to see what the main reason was for a patient to stop with his/her medication. Most patients mentioned side effects as the reason why they stopped using their medicine or switched to another medicine. Not all returned questionnaires could be analysed. Sixty-three percent of the respondents mentioned the correct name of the medicine they started 6 months ago. A possible explanation could be that the patient had started more than one medicine at that time. As noted above, the pharmacists mentioned that some patients also had questions about other medicines they use, and these medicines were also discussed during the consultation moment. This could be another explanation for why the patient mentioned the wrong name of the medicine in the questionnaire. Because of the low number of analysed questionnaires, it was not possible to examine the differences in answers between intervention and control group.

4.2. Conclusion

Pharmacists and patients are positive about the implementation of the concordance model in Dutch community pharmacies. The concordance form was found to be a useful tool to start a patient consultation based on patient needs.

There is no significant difference in adherence to medication between patients in the intervention or control group. However, the adherence in the control group with 79% is already high. These results suggest that the use of the concordance form followed by a consultation at the second dispensing has no significant effect on adherence to chronic drug use.

4.3. Practice implications

Analysis of the written answers on the concordance forms shows that there are five questions which provide the most answers and are considered most relevant. In future studies, it can be considered that only these five selected questions instead of the initial 10 questions on the concordance form shall be used. A second recommendation is to include only one drug group or select a larger number of patients so it is possible to divide the patients into different drug groups. Finally, more consultation moments during a certain time period is recommended.

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